# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant:

Yoav KIMCHY et al.

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For:

Ingestible Pill

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Examiner:

Elmer M. CHAO

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# **APPEAL BRIEF (37 C.F.R. §41.37)**

Sir:

This brief is further to a Notice of Appeal filed on November 16, 2009.

This Appeal Brief is being filed on January 19, 2010 (January 16, 2010 being Saturday, and January 18, 2010 being Martin Luther King's Birthday), and for which no extension of time fee is due.

# REAL PARTY OF INTEREST

The real party in interest of this appeal is the following party: Spectrum Dynamics LLC.

# RELATED APPEALS AND INTERFERENCES

This appeal has no related proceedings or interferences.

# **STATUS OF CLAIMS**

# A. TOTAL NUMBER OF CLAIMS IN THE APPLICATION

The claims in the Application are: 1-19.

# B. STATUS OF ALL THE CLAIMS IN THE APPLICATION

Claims cancelled: 5.

Claims withdrawn from consideration but not cancelled: 9-15.

Claims pending: 1-4, 6-8 and 16-19.

Claims allowed: NONE

Claims rejected: 1-4, 6-8 and 16-19.

Claims objected to: NONE

# C. CLAIMS ON APPEAL

The claims on appeal are: 1-4, 6-8 and 16-19.

# **STATUS OF AMENDMENTS**

An Amendment after Final Rejection dated July 15, 2009 was not filed. Therefore, claims 1-4, 6-8 and 16-19 on appeal herein are as amended in the Response to Office Action filed on April 7, 2009.

#### SUMMARY OF CLAIMED SUBJECT MATTER

The appealed independent claims in the Application are claims 1 and 16, which are repeated below with reference to passages in the application as filed providing support, in bold letters.

Independent claim 1 defines a system for diagnosing a gastrointestinal tract, comprising:

an ingestible device, arranged for traveling within a gastrointestinal tract of a body, comprising:

a probe, operative to acquire, along said gastrointestinal tract, a diagnostic image of nuclear radiation of a radiopharmaceutical; {page 20, lines 7-8; page 39, lines 27-28 and Figs. 2A-2B}

data-handling apparatus, in signal communication with said probe, for receiving and handling imaging data, generated by said probe; {page 20, lines 9-10; page 39, line 32 – page 40, line 1 and Figs. 2A and 2B}

a power source, for powering said probe and data-handling apparatus; and {page 20, line 11; page 40, line 14 and Figs. 2A-2B}

a shell, which encapsulates said probe, data-handling apparatus, and power source within, {page 20, lines 12-13; page 40, lines 16-19 and Figs. 2A-2B}

wherein said ingestible device comprises a plurality of nuclear-radiation detectors, arranged around said probe, and {page 63, lines 25-31 and Fig. 21}

circuitry comprising at least one sensor adapted to determine the location and orientation of the ingestible device in the gastrointestinal tract and the circuitry is further adapted to reconstruct the diagnostic image based on said location and orientation. {page 43, line 22 - page 44, line 30 and Figs. 3A-3D}

Independent claim 16 defines a method of diagnosing a gastrointestinal tract, the method comprising:

inserting an ingestible device comprising a probe and a sensor into a gastrointestinal tract of a body; {page 39, line 25 - page 40, line 13 and Figs. 2A-2B}

collecting diagnostic imaging data along said gastrointestinal tract by detecting nuclear radiation of a radiopharmaceutical using a plurality of nuclear radiation detectors, said nuclear radiation detectors are arranged around said probe; {page 39,

line 25 - page 40, line 13; page 52, lines 28-32; page 63, lines 25-31 and Figs. 2A-2B, 10A-10B and 21}

determining the location and orientation of the ingestible device in the gastrointestinal tract by said sensor; and {page 43, line 22 - page 44, line 30 and Figs. 3A-3D}

reconstructing a diagnostic image from said collected imaging data based on said location and orientation. {page 43, line 22 - page 44, line 30 and Figs. 3A-3D}

Dependent claims 8, 17 and 18 are separately argued by applicant and are repeated below with reference to passages in the Application as filed providing support, in bold letters.

Dependent Claim 8 defines system of claim 1, wherein said ingestible device is arranged as a compton camera. {page 63, line 32 - page 64, line 3}

Dependent Claim 17 defines a system according to claim 1 wherein said ingestible device is sized to be swallowed. {page 46, lines 22-25}

Dependent Claim 18 defines a system according to claim 1 wherein said ingestible device is shaped as a pill. {title and Figs. 1-24}

Dependent Claim 19 defines a system according to claim 1, wherein said ingestible device further comprises a transmitter for transmitting data to said at least one sensor, wherein the at least one sensor determines the location and orientation of the ingestible device in the gastrointestinal tract based on said data. {page 43, lines 27-32}

# GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

# A. GROUND OF REJECTION 1 (CLAIMS 1-4, 6, 7 AND 16)

Claims 1-4, 6, 7 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,076,009 to Raylman et al (herein "Raylman '009") in view of US 6,236,880 to Raylman et al (herein "Raylman '880").

# B. GROUND OF REJECTION 2 (CLAIM 8)

Claim 8 stands rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,076,009 to Raylman et al in view of US 6,236,880 to Raylman et al (herein "the *Raylman* references") and further in view of Zhang et al., Society of Nuclear Medicine (herein "Zhang").

# C. GROUND OF REJECTION 3 (CLAIMS 17-19)

Claims 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,076,009 to Raylman et al in view of US 6,236,880 to Raylman et al (herein "the *Raylman* references") and further in view of US 6,632,216 to Houzego et al (herein "*Houzego*").

#### **ARGUMENTS**

# A. GROUND OF REJECTION 1 (CLAIMS 1-4, 6, 7 AND 16)

Claims 1-4, 6, 7 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,076,009 to Raylman et al (herein "Raylman '009") in view of US 6,236,880 to Raylman et al (herein "Raylman '880"). Claims 1 and 16 are the only independent claims pending in the application.

#### A.1 Rejection of Claims 1 and 16

In rejecting claim 1, the Examiner stated the following in the Final Office Action:

Raylman '009 teach an ingestible device (fig. 2, item 1) for diagnosing body cavities comprising: a probe, operative to acquire, along said gastrointestinal tract (col. 19, lines 35-40), a diagnostic image of nuclear radiation of a radiopharmaceutical (col. 19, lines 40-44); data-handling apparatus, in signal communication with said probe, for receiving and handling imaging data, generated by said probe (fig. 2, item 13); a power source, for powering said probe and data-handling apparatus, and power source within (fig. 4, item 70), wherein said ingestible device comprises a plurality of nuclear-radiation detectors, arranged around said probe (fig. 8 & 9, items 30 & 40; col. 19, lines 40-44), wherein the nuclear radiation detectors are arranged for detecting gamma and beta radiation (col. 3, lines 61-65).

Raylman '009 teach the limitations as discussed above but fail to explicitly teach circuitry with a sensor to determine location and orientation of the ingestible device.

However, in the same field of endeavor, Raylman '880 teach determining location and orientation of the tip of the ingestible device (col. 9, lines 62-67, refer to the operator determining the orientation). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to automate the process of determining the location and orientation of the tip of the ingestible device in order to free the operator of the task. Such a modification is considered automating a manual activity (for motivation see In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194) and can be conducted with surgical tracking systems well-known in the art.

[Final Office Action dated July 15, 2009, page 5]

# A.2 Claim 1 Distinguishes over Cited References

Appellants respectfully submit that the Examiner has not provided a *prima* facie case of obviousness against independent claim 1. Specifically, the Examiner failed to show the following features of claim 1 in the cited references:

- (1) an ingestible device, arranged for traveling within a gastrointestinal tract of a body (hereinafter "Feature (1)").
- a shell, which encapsulates said probe, data-handling apparatus, and power source within (hereinafter "Feature (2)").
- (3) circuitry comprising at least one sensor adapted to determine the location and orientation of the ingestible device in the gastrointestinal tract and the circuitry is further adapted to reconstruct the diagnostic image based on said location and orientation. (hereinafter "Feature (3)").

# A.3 Feature (1) of Claim 1 Distinguishes over Cited References

Feature (1) of claim 1 recites that the claimed system comprises an ingestible device, arranged for traveling within a gastrointestinal tract. Both *Raylman* '009 and *Raylman* '880 describe endoscopic devices which are not ingested into the gastrointestinal tract but adapted to be held by a surgeon during examination of the gastrointestinal tract.

Raylman '009 describes for example in col. 11, lines 5-19 that a portion of the device is placed in the body while another portion of the device remains outside the body. Raylman '880 also teaches a device that constitutes of a body portion and a handle portion, see col. 5, lines 13-23.

Appellants have presented this argument in a previous response filed on April 7, 2009 upon which the Examiner replied the following in the Final Office Action:

Regarding Applicants' arguments with respect to claims 1-4 and 6-19, Applicants argue that Raylman '009 does not teach an ingestible device (page 7, paragraphs 4 & 5, Remarks field 4/7/2009). Even though Raylman '009's probe is used while a portion of the probe is outside the body being held by a hand, the other portion of the probe can still be considered ingested if used inside the throat, esophagus, or GI tract. Therefore, the probe can still be considered ingestible. By Applicants claiming "an ingestible device", they do not preclude a device that is partially ingestible. Furthermore, it can be argued that Raylman '009's entire device is ingestible. Just because a device might be used for a certain purpose does not make it non-ingestible. There are several known examples of items that are not intended to be ingested but still end up being ingested by a motivated human, oftentimes children, and at other times thrill-seeking adults.

[Final Office Action dated July 15, 2009, page 7]

The Examiner provides two arguments, first that the portion of the probe of the endoscope can be considered as ingested and second that thrill seeking adults ingest device that are not intended for ingestion.

Regarding the first argument provided by the Examiner, appellants provide a definition of ingestible as copied from Webster's Encyclopedic Unabridged Dictionary of the English Language, attached herewith as Annex A:

"ingest v.t. - 1. to take, as food, into the body (opposed to egest)
2. Aeron, to draw (foreign matter) into the inlet of a jet engine, often causing damage to the engine.

ingestible, adj. – ingestion, n. – ingestive, adj."
[definition of ingest from Webster's Encyclopedic Unabridged Dictionary of the English Language, 1996 Edition]

The definition applicable to claim 1 is the first one – to take as food into the body. Like food that cannot be taken into the body when a part attached thereto remains outside of the body, also the prior art teachings of an endoscope of which part of the device is left outside of the body cannot be ingested into the body. Accordingly appellants submit that the prior art teachings of Raylman '009 and Raylman '880 do not meet the language of Feature (1) reciting an "ingestible device".

Regarding the second argument provided by the Examiner according to which

thrill-seeking adults ingest about everything, appellants respectfully submit that in order to ingest a device as large as an endoscope, the device must be cut into pieces. However, such a cut into pieces device does not meet the rest of the claim requirements, such as for example "circuitry comprising at least one sensor adapted to determine the location and orientation of the ingestible device in the gastrointestinal tract and the circuitry is further adapted to reconstruct the diagnostic image based on said location and orientation." The circuitry of the device cannot determine location and orientation of the device which is cut into pieces. Thus, appellants submit that the second argument of the Examiner is also erroneous.

Accordingly, it is submitted that *Raylman* '009 and *Raylman* '880, alone or in combination, fail to teach or suggest Feature (1) of claim 1.

# A.4 Feature (2) of Claim 1 Distinguishes over Cited References

Feature (2) of Claim 1 recites that the system comprises a shell, which encapsulates the probe, data-handling apparatus, and power source within.

The Examiner failed to refer to Feature (2) in his rejection. Appellants respectfully submit that Feature (2) is not found in the Examiner's interpretation of Raylman '009 or Raylman '880.

The claimed features of probe, data-handling apparatus and power source are indicated by the Examiner as present in *Raylman* '009 as elements 1, 13 and 7 respectively. (The Examiner indicated that the power source is found in *Raylman* '009 as element 70 in Fig. 4. However since there is no element 70 in *Raylman* '009 it is assumed that the Examiner intended to indicated element 7 in Fig. 1 which is a power supply).

Elements 1, 13 and 7 are shown in Figs. 1 and 2 of *Raylman* '009. As can be seen in Figs. 1 and 2 provided below, the elements are not encapsulated within a shell and are separate parts of the system.

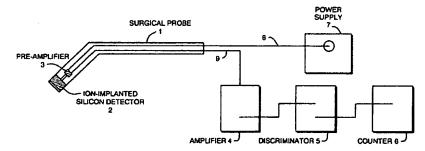
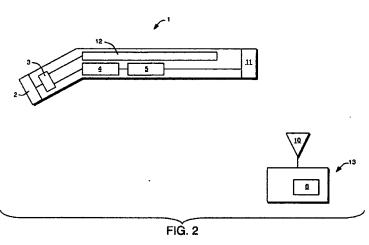


FIG. 1



[Raylman '009, Figs. 1 and 2]

Raylman '009 states in col. 12, lines 49-51 that elements 4-7 can be housed within the same system. However, processing means 13 is located outside of probe 1. No where in Raylman '009 is there a suggestion of providing processing means 13 in the handheld probe.

Appellants submit that the Feature (2) is also not found in the Examiner's interpretation of *Raylman* '880 where a similar structure of an endoscope is taught. Power and analysis unit 30 in *Raylman* '880 corresponds to processing means 13 in *Raylman* '009. As can be seen for example Fig. 4 of *Raylman* '880 provided below, power and analysis unit 30 is separate from the endoscope and is not encapsulated within one shell with the rest of the features.

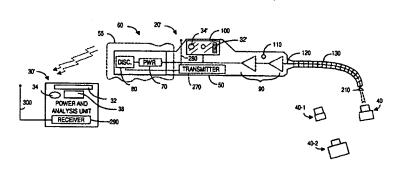


FIG. 4

[Fig. 4 of Raylman '880]

Accordingly, it is submitted that the Examiner erred in his rejection and failed to show Feature (2) of claim 1 in *Raylman* '009 or *Raylman* '880, alone or in combination.

# A.5 Feature (3) of Claim 1 Distinguishes over Cited References

Feature (3) of claim 1 recites that the system comprises circuitry comprising at least one sensor adapted to determine the location and orientation of the ingestible device in the gastrointestinal tract and the circuitry is further adapted to reconstruct the diagnostic image based on said location and orientation.

The Examiner admits in the Final Office Action that Feature (3) is not disclosed in *Raylman* '009. However, the Examiner asserts that Feature (3) is found in col. 9, lines 62-67 of *Raylman* '880 where it is taught that the operator determines the orientation of the device.

Appellants respectfully disagree. Following is a quotation of the referred paragraph:

"To recapitulate, the present invention provides a probe system in which probe tips may readily be attached or detached from the distal end of a curved, preferably flexible tube that is affixed to the probe handle or body. The operator or other practitioner-user can thus adjust the orientation of an appropriate detector tip for the task at hand."

[Raylman '880, col. 9, lines 62-70]

The cited section describes that due to the flexible tube (or wireless device as mentioned in other embodiments of the document), the operator can orient the device according to the task at hand. However, appellants submit that there is no disclosure in *Raylman* '880 for a circuitry as recited in Feature (3).

According to the Examiner, it would have been obvious to a person of ordinary skill in the art to automate the process of determining the location and orientation of the tip of the ingestible device in order to free the operator from the task. The Examiner further states that such a modification is considered automating a manual activity and can be conducted with surgical tracking systems well known in the art. For motivation, the Examiner refers to In re Venner, 262 f. 2d 91, 95, 120 USPQ 193, 194.

It is assumed that the Examiner relied in his rejection on the following statement by the U.S. Court of customs and Patent Appeals in In re Venner:

"...we believe it to be a settled rule that it is not invention to produce a device which is within the realm of performance of a skilled mechanic in the ordinary progress of producing a device required to effectuate a given result." (emphasis added)

[In re Venner, 262 f. 2d 91, 95, 120 USPQ 194]

As shown above, the orientation of the device in *Raylman* '880 is adjusted or oriented by the practitioner, while the practitioner is holding the handheld device and performing the task at hand. Automating such orientation would provide no advantage since it could not free the practitioner from the task of holding the handheld device. At most, such automating would involve unnecessary complications to the handheld device. Thus, a person of ordinary skill in the art would have been taught against automating the adjustment of the device as taught in *Raylman* '880.

In addition, even if automating the practitioner's adjustment is considered obvious, and appellants object thereto, the teachings of *Raylman* '880 still do not meet the requirements of Feature (3) of claim 1 which recites "circuitry comprising at least one sensor adapted to determine the location and orientation of the ingestible device in the gastrointestinal tract and the circuitry is further adapted to reconstruct the diagnostic image based on said location and orientation." (emphasis added)

The adjustment in Raylman '880 and the circuitry in the present claims are different tasks which effectuate a different result. The reason therefore is that the adjustment as taught in Raylman '880, whether automated or manually performed, is an adjustment of a handheld device and not of an ingestible device as claimed. The location and orientation of a handheld device, as Raylman's device, are controlled by the practitioner and is a relatively simple task. In fact, such an adjustment by a practitioner is an integral part of holding the device by the practitioner. However, determining the orientation and location of an ingestible device which is freely traveling in the gastrointestinal tract, without being completely controlled by any source, is a complicated and totally different task.

Thus, automating the adjustment taught in *Raylman* '880 does not effectuate a same result as the circuitry recited in Feature (3).

Accordingly, it is submitted that *Raylman* '009 and *Raylman* '880, alone or in combination, fail to teach or suggest Feature (3) of claim 1.

# A.6 Claim 16 Distinguishes over Cited References

Appellants respectfully submit that the Examiner has not provided a *prima* facie case of obviousness against claim 16. Specifically, the Examiner failed to show the following features of claim 16 in the cited references:

(1) inserting an ingestible device comprising a probe and a sensor into

- a gastrointestinal tract of a body.
- (2) determining the location and orientation of the ingestible device in the gastrointestinal tract by said sensor; and reconstructing a diagnostic image from said collected imaging data based on said location and orientation.

The first feature of claim 16 recited above incorporates subject matter which is similar to the subject matter Feature (1) of claim 1 and is patentable at least for the reasons described in chapter A.3 above.

The second feature of claim 16 recited above incorporates subject matter which is similar to the subject matter of Feature (3) of claim 1 and is patentable at least for the reasons described in chapter A.5 above.

Accordingly, it is submitted that *Raylman* '009 and *Raylman* '880, alone or in combination, fail to teach or suggest the recited features of claim 16.

# B. GROUND OF REJECTION 2 (CLAIM 8)

Claim 8 stands rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,076,009 to Raylman et al in view of US 6,236,880 to Raylman et al (herein "the *Raylman* references") and further in view of Zhang et al., Society of Nuclear Medicine (herein "*Zhang*").

# **B.1 Rejection of Claim 8**

In rejecting claim 8, the Examiner stated the following in the Final Office Action:

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raylman '009 in view of Raylman '880 as applied to claim 1 above, and further in view of Zhang et al. (Society of Nuclear Medicine, June 2000). Raylman '009 and Raylman '880 teach the limitations as discussed above but fail to explicitly teach an ingestible device arranged as a Compton camera. However, in the same field of endeavor, Zhang teaches a transrectal imaging probe based on Compton camera techniques (No. 68, second sentence). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the invention to include a Compton camera probe as evidenced by Zhang. Such a modification would allow the ingestible device to have high sensitivity and high resolution (No. 68, second sentence).

[Final Office Action dated July 15, 2009, page 6]

#### **B.2** Combination of References would not result in claimed invention

The Examiner failed to provide a *prima facie* case of obviousness against claim 8, since the Final Office Action did not show how a combination of the *Raylman* references with *Zhang* would result in the claimed invention.

As detailed in chapter A.3 above, the *Raylman* references fail to teach an ingestible device as recited in claim 8 (which depends from claim 1). In addition, *Zhang* does not teach an ingestible device. In fact, as will be shown below, *Zhang* teaches against implementing its teachings in an ingestible device. Thus, a combination of the *Raylman* references with *Zhang* would not result in an ingestible device as claimed.

Zhang discloses an imaging probe which is used in conjunction with CZT cameras located below and above the body (No. 68, Col. 1). Zhang does not refer to

an ingestible device as recited in claim 8.

A Compton camera as described in *Zhang* requires two detectors onto which a photon is absorbed and scattered. The scattering angle is then calculated using the Compton formula. *Zhang* uses CZT cameras as the second detectors (No. 68, Col. 1). In order to calculate the scattering angle using CZT cameras as described in *Zhang*, the detectors should be relatively large and be positioned relatively far from each other in order to differentiate between the detections from the different detectors.

Zhang provides exemplary dimensions of the detectors which show that such detectors have large dimensions and could not be used with an ingestible device as claimed. Zhang describes the first detector to be about 1X4X1 cm³ large and the second detectors (CZT cameras) to be about 40X40X2 cm³ large. In addition, the CZT cameras in Zhang are placed 5cm below and above the body (No. 68, Col. 1). Clearly, such detectors cannot be implemented in an ingestible device as recited in claim 8. Accordingly, a person of ordinary skill in the art would be taught against implementing the Compton camera of Zhang in an ingestible device as claimed in claim 8.

It is further noted that claim 8 depends on claim 1 and is patentable at least for the reasons described in chapter A above. The imaging probe disclosed in *Zhang* does not disclose any of Features (1), (2) or (3) of claim 1.

# C. GROUND OF REJECTION 3 (CLAIMS 17-19)

Claims 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,076,009 to Raylman et al in view of US 6,236,880 to Raylman et al (herein "the *Raylman* references") and further in view of US 6,632,216 to Houzego et al (herein "*Houzego*").

#### C.1 Rejection of Claims 17-19

In rejecting claims 17-19, the Examiner stated the following in the Final Office Action:

10. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raylman '009 in view of Raylman '880, and further in view of Houzego et al. (U.S. 6,632,216 B2). Raylman '009 and Raylman '880 teach the limitations as discussed above but fail to explicitly teach the ingestible device being shaped and sized as a swallowable pill with orientation and location transmitting capabilities. However, in the same field of endeavor, Houzego et al. teach an ingestible device being shaped and sized as a swallowable pill with orientation and location-tracking capabilities (col. 1, liens 40-44; col. 7, lines 43-49). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use an ingestible device being shaped and sized as a swallowable pill with orientation and location tracking capabilities or order to reach a chosen location in the gastrointestinal tract of a mammal (for motivation see col. 1, lines 10-25).

[Final Office Action dated July 15, 2009, pages 6-7]

# C.1 No Basis for Combining References

The Examiner failed to provide a *prima facie* case of obviousness against claims 17-19, since the Final Office Action did not state a proper reason to combine the *Raylman* references with *Houzego*.

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR International Co. v. Teleflex Inc. (KSR), 82 USPQ2d 1385 (2007).

For motivation to combine the *Houzego* reference with the *Raylman* references the Examiner refers to col. 1, lines 10-25 of *Houzego*. This section is part of the background section of *Houzego* and states:

"The present invention relates to an ingestible device. In particular the invention relates to such a device in the form of a capsule that is intended to release a controlled quantity of a substance, such as a pharmaceutically active compound, foodstuff, dye, radiolabelled marker, vaccine, physiological marker or diagnostic agent at a chosen location in the gastrointestinal (GI) tract of a mammal. Such a capsule is sometimes referred to as a "Site-Specific Delivery Capsule", or SSDC.

SSDC's have numerous uses. One use of particular interest to the pharmaceutical industry involves assessing the absorption rate and/or efficacy of a compound under investigation, at various locations in the GI tract. Pharmaceutical

companies can use data obtained from such investigations, e.g. to improve commercially produced products."

[*Houzego*. Col. 1, lines 10-25]

In the recited section, *Houzego* refers to Site-Specific Delivery Capsule, also called SSDC, and its uses. However, there is no teaching in this section or in any other section of *Houzego* to support a rational underpinning of providing the devices of *Raylman* sized to be swallowed or shaped as a pill as claimed in claims 17 and 18 respectively.

While *Houzego* states in the background section quoted above that the SSDC devices can be used for asserting the absorption rate of a compound, *Houzego* does not refer to adding a detector to the SSDC. Appellants submit that the use which *Houzego* suggest for the SSDC is the position of detectors or cameras outside the body which will image the body portion where the SSDC released the compound and thereby assert the absorption thereof. There is no teaching or suggestion in *Houzego* to add a detector to such an SSDC. Moreover, due to the size constraints of the ingestible SSDC, it teaches against adding an additional camera thereto, since adding a camera that is positioned in the SSDC fills space in the SSDC and necessarily causes the SSDC to include a smaller amount of compound for releasing in the body.

Not only does *Houzego* not provide a rational underpinning and in fact teaches against the combination of references suggested by the Examiner, the *Raylman* references also teach against doing so. A person of ordinary skill in the art, reading the *Raylman* references would be taught against transforming the devices of the *Raylman* references into a device as claimed in claims 17 and 18.

The endoscopes disclosed in the *Raylman* references are adapted to be controlled by a practitioner. Modifying these endoscope to an ingestible device which is sized to be swallowed or shaped as a pill would harm the functionality of the endoscopes. Such modification would involve drawbacks with which the *Raylman* references do not confront. For example, no full control of the orientation and direction of the device, no control of the time period that the device is in a specific location and significant size constraints.

In addition, *Raylman* '880 teaches away from using an ingestible device, since his device is adapted for replacing of the probe tips by the medical practitioner during the course of a procedure, as described in col. 3, lines 1-7. This could not be done

with a device that is ingested, since it is not available to the practitioner during the procedure.

Claim 19 recites "wherein said ingestible device further comprises a transmitter for transmitting data to said at least one sensor, wherein the at least one sensor determines the location and orientation of the ingestible device in the gastrointestinal tract based on said data". It is submitted that the Examiner did not relate to the features of claim 19 in his rejection. However, appellants note that neither *Houzego* nor the *Raylman* references teach or suggest a transmitter as recited in claim 19.

It is further stated that *Houzego* is not in the same field of endeavor as the *Raylman* references. *Houzego* refers to an ingestible device which is adapted to release a substance in a chosen location in the gastrointestinal tract. There is no teaching or suggestion in *Houzego* to use the ingestible device with nuclear radiation detectors.

The *Raylman* references both refer to endoscopic devices having radiation detectors, where the endoscopic devices are adapted to be used when part of the device is left outside the body (see chapter A.3 above).

Furthermore, the Federal Circuit in *In re Vaek, 20 USPQ2d 1438 (1991)* stated that the suggestion to make the claim combination must be found in the prior art and not in appellant's disclosure. There would be no reason or motivation for a person of ordinary skill in the art at the time of the invention to combine the endoscopic devices of *Raylman* with the ingestible device of *Houzego*. Such a suggested combination is based on hindsight only.

## **Conclusion**

Claims 1-4, 6-8 and 16-19 are believed to patentable distinguish over *Raylman* '009, *Raylman* '880, *Zhang* and *Houzego*, in any combination, for at least all of the above reasons. Therefore, it is respectfully requested that the Board reverse the Examiner's Final Rejection for those claims.

Appellants are separately arguing the patentability of independent claims 1 and 16 and dependent claims 8 and 17-19. The other pending claims are patentable at least by virtue of their dependency on a patentable parent claim.

Respectfully submitted,

Marla O, Morrish

Martin D. Moynihan Registration No. 40,338

Date: January 19, 2010

#### **CLAIMS APPENDIX**

The text of the claims on appeal is as follows:

1. A system for diagnosing a gastrointestinal tract, comprising:

an ingestible device, arranged for traveling within a gastrointestinal tract of a body, comprising:

a probe, operative to acquire, along said gastrointestinal tract, a diagnostic image of nuclear radiation of a radiopharmaceutical;

data-handling apparatus, in signal communication with said probe, for receiving and handling imaging data, generated by said probe;

a power source, for powering said probe and data-handling apparatus; and

a shell, which encapsulates said probe, data-handling apparatus, and power source within,

wherein said ingestible device comprises a plurality of nuclearradiation detectors, arranged around said probe, and

circuitry comprising at least one sensor adapted to determine the location and orientation of the ingestible device in the gastrointestinal tract and the circuitry is further adapted to reconstruct the diagnostic image based on said location and orientation.

- 2. The system of claim 1, wherein at least one of said nuclear-radiation detectors is arranged for detecting gamma and beta radiation.
- 3. The system of claim 2, wherein said at least one nuclear-radiation detector is gated substantially to a photon energy associated with a particular radioisotope.
- 4. The system of claim 2, wherein said at least one nuclear-radiation detector is gated substantially to at least two photon energies associated with two particular radioisotopes.

. \* .

- 6. The system of claim 1, wherein some of said plurality of nuclearradiation detectors may be gated substantially to a photon energy associated with a specific radioisotope, while others may be gated substantially to a photon energy associated with a different radioisotope.
- 7. The system of claim 2, wherein said at least one nuclear-radiation detector is not collimated, to detect nuclear radiation impinging at any angle.
- 8. The system of claim 1, wherein said ingestible device is arranged as a compton camera.
- 16. A method of diagnosing a gastrointestinal tract, the method comprising:

inserting an ingestible device comprising a probe and a sensor into a gastrointestinal tract of a body;

collecting diagnostic imaging data along said gastrointestinal tract by detecting nuclear radiation of a radiopharmaceutical using a plurality of nuclear radiation detectors, said nuclear radiation detectors are arranged around said probe;

determining the location and orientation of the ingestible device in the gastrointestinal tract by said sensor; and

reconstructing a diagnostic image from said collected imaging data based on said location and orientation.

- 17. A system according to claim 1 wherein said ingestible device is sized to be swallowed.
- 18. A system according to claim 1 wherein said ingestible device is shaped as a pill.
- 19. A system according to claim 1, wherein said ingestible device further comprises a transmitter for transmitting data to said at least one sensor, wherein the at least one sensor determines the location and orientation of the ingestible device in the gastrointestinal tract based on said data.

# EVIDENCE APPENDIX

This appeal has no evidence appendices.

# RELATED PROCEEDINGS APPENDIX

This appeal has no related proceedings.

# WEBSTER'S ENCYCLOPEDIC UNABRIDGED DICTIONARY OF THE ENGLISH LANGUAGE



The dictionary entries are based on the Second Edition of The Random House Dictionary of the English Language

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in-fun-dib-u-ium (in/fun dib/yə ləm), n., pl. -la (-lə).

Anat. 1. a funnel-shaped organ or part. 2. a funnel-shaped extension of the hypothalamus connecting the pigland to the base of the brain. 3. a space in the tuitary gland to the base of the brain. 3. a space in the right ventricle at the base of the pulmonary artery. [1700-10; < NL, L. funnel, equiv. to infundi- (s. of infundere to pour into; see in-, round) + -bulum instrumental suffix; cf. inruss]—infun-dib'u-ler, in-fun-dibu-let (in/fun dib'yə lāt'), adj.

in-fu-ri-ate (v. in-fu-ri-ate), adj. in fyōor's it), v., at-ed, at-ing, adj. —v.t. 1. to make furious; enrage. —adj. 2. Archaic. infuriated. [1660-70; All. in-fu-ri-ate-ity, adv. —in-fu-ri-ate-ity, ation, n.
—Syn. 1. anger. See enrage.

In-fu-ri-at-ing (in fy85r/8 a/ting), adj. causing or tending to cause anger or outrage; maddening. His delay is infuriating. [1880-85; INFURIATE + -ING<sup>2</sup>] —in-fu/ri-at/ing-iy. adv.

in-fus-cate (in fus/kāt, -kit), adj. Entomol. darkened with a fuscous or brownish tinge. Also, In-fus/cat-ed. [1640-50; < L infuscus ptp. of infuscare to darken, discolor. See in-\*, fuscous, -ATE\*]

color. See IN-2, FUSCOUS, LATE!]

in-fuse (in fyo50z), w., -fused, -fus-ing, —v.t. 1. to introduce, as if by pouring; cause to penetrate; instill (usually fol. by into): The energetic new principal infused new life into the school. 2. to imbue or inspire (usually fol. by with): The new coach infused the team with entusiasm. 3. to steep or soak (leaves, bark, poots, etc.) in a liquid so as to extract the soluble properties or ingredients. 4. Obs. to pour in. —v.i. 5. to undergo infusion; become infused: Leave the solution to infuse overnight. [1375-1425; late ME < L infusus ptp. of infunder to pour into. See IN-2, Pusz!] —in-fusy'er, n.—Syn. 1. ingrain; inculcate.

in-fu-si-ble¹ (in fy55/2a bel), adj. not fusible; incapable of being fused or melted. [1545-55; IN-² + FUSIBLE]
—in-fu/si-bil/i-ty, in-fu/si-ble-ness, n.

in-fu-si-ble<sup>2</sup> (in fy55/2s bel), adj. capable of being in-fused. [1650-60; INFUSE + -IBLE]

fused. [1650-60; INFUSE + -IBLE]

In-fu-Sion (in fy85 zhen), n. 1. the act or process of infusing. 2. something that is infused. 3. a liquid extract, as tea, prepared by steeping or soaking. 4. Pharm. a. the steeping or soaking of a crude drug in water. b. the liquid so prepared. 5. Med. a. the introduction of a saline or other solution into a vein. b. the solution used. [1400-50; late ME < L infusion-(a. of infusio). See INFUSE, -ION]

|n-fu-sion-ism (in fyo5/2h niz/em), n. Theol. the doctrine that the soul existed in a previous state and is infused into the body at conception or birth. [1880-85; INFUSION + -ISM] —Infu/sion-ist, n.

in-fu-sive (in fy65'siv), adj. capable of infusing; inspiring. [1620-30; infuse + -ive]

spiring. [1620-30; INFUSE + -1VE]

8n-fu-So-ri-2 (in/fyōō chi-5 a, -sōr'-), n.pl. 1. protozons of the phylum Ciliophora (or class Ciliata). 2.

(formerly) any of various microscopic organisms found in
infusions of decaying organic matter. [1780-90; < NL,
neut. pl. of infusorius. See INFUSE, -ony\*]

in-fu-so-ri-al (in/fyos sore ol, -sor/-), adj. pertaining to, containing, or consisting of infusorians: infusorial earth. [1840-50; INPUSORI(A) + -AL']

in-fu-so-ri-an (in/fyon cor/s an, -sor/-), n. 1. any of the Infusoria. -adj. 2. (ufusorial. [1855–60; In-rusoriah. + -an]

In futuro (in 656 t55/n5; Eng. in fy66 t56/s, ty66/s), Latin. in the future.

-ing., a suffix of nouns formed from the expressing terial etc.

"a machine for sewing." Cf. Ing. [ME, OE -ing, -ung] -ing., a suffix forming the present participle of verbs, walking; thinking), such participles being often used as participlat adjectives: warring factions. Cf. -ing.' [ME -ing, -inge; the var. -in (usually represented in sp. as -in.') continues ME -inde, -ende, OE -ende]

—Pronunciation. The common suffix -ing' can be pronuncied in modern English as either (-ing) or (-in), with either the velar nasal consonant (ng), symbolized in IPA as [n], or the alveolar nasal consonant (n), symbolized in IPA as [n]. The (-in) pronunciation therefore reflects the use of one nasal as against another and not, as is popularly supposed, "dropping the g." since no actual g-sound is involved.

Many speakers use both pronunciations, depending on

sound is involved.

Many speakers use both pronunciations, depending on
the speed of utterance and the relative formality of the
occasion, with (-ing) considered the more formal variant.
For some educated speakers, especially in the southern
United States and Britain, (-in) is in fact the more common pronunciation, while for other educated speakers,
(-ing) is common in virtually all circumstances. In response to correction from perceived authorities, many American speakers who would ordinarily use (-in) at least some of the time make a conscious effort to say the time make a conscious effort to say (-ing), even in informal circumstances

"Ing", a native English suffix, meaning "one belonging to," "of the kind of," "one descended from," and sometimes having a diminutive force, formerly used in the formation of nouns: farthing; shilling; bunting; gelding; whiting, Cf. -ling.' [ME, OE -ing; c. ON -ingr, -ungr, Goth -ings]

in-gate (in/gat/), n. Metall. gate (def. 15). [1855-60; IN + GATE ]

In-gath-er (in/gath er, in gath/er), v.t. 1. to gather or bring in, as a harvest. —v.t. 2. to collect; assemble. [1565-75; IN-1 + GATHER] —in-gath/er-er, n.

In-gath-er-ing (in/gath/er ing), n. 1. a gathering in, esp. of farm products; harvest. 2. a gathering together, as of persons; assembly. [1525-35; IN-1 + GATHERING]

Ingo (inj for I: ing for 2), n. 1. William (Motter) (mot/er), 1913-73, U.S. playwright. 2. William Ralph, 1860-1954, Anglican clergyman, scholar, and author: dean of St. Paul's 1911-34.

in-ge-low (in/is lo/), n. Jean. 1820-97. English poet and novelist.

ing-e-mar (ing/ge mar/), n. a male given name

in-gem-i-nate (in jem's nat'), u.t., -nat-ed, -nat-ing, to repeat; reiterate. [1585-95; < L ingeminatus ptp. of ingeminatus to repeat, redouble. See IN-\*, GEMINATE]
—in-gem'i-na'tion, n.

in-gen-er-ate (in jen/ər it), adj. not generated; self-existent. [1650-60; < LL ingeneratus not begotten. See

existent. [1600-60]; < LL ingeneratus not begotten. See IN.-3, CENERATE] In-gen-er-ate<sup>2</sup> (v. in jen'e rät'; adj. in jen'ar it), v., -st-ed, -st-ing, adj. — v.t. 1. to engender, produce, -adj. 2. inborn; innate. [1625-35]; < L ingeneratus ptp. ot ingeneratus ptp. ot

tion, n.

in-gen-lous (in jön/yes), adj. 1. characterized by cleverness or originality of invention or construction: an ingenious machine. 2. cleverly inventive or resourceful: an ingenious press agent. 3. Obs. a. intelligent; showing genius. b. ingenious. [1376-1425; late ME < 1 ingenious. [1376-1425; late ME < 1 ingenious. [1376-1425; late ME < 1 ingenious. [138-140]. In the construction, cleverness (in. IN-" + gen. (base of gignere to bring into being; cf. Osmron) + ium. rulm + fosus ous] — ingen/lous-by. adv. —ingen/lous-ness, n.
—Syn. 2. bright, gifted, able, resourceful; adroit.—Ant. 2. unskilful.

—Ant. 2. unskilfful.

—Usage. Ingenious and ingenious are now distinct from each other and are not synonyms. Ingenious means "characterized by cleverness" or "cleverly invenive," as in contriving new explanations or methods: an ingenious device; ingenious designers. Ingenious means "candid" or "innocent": an ingenious and sincere statement; a thug with the ingenious eyes of a choirboy.

ment; a ring with the ingenuous eyes of a choirooy.

ingé-nue (an/zhe noo, -nyoō/; Fr. an xha ny/), n., pl.

-nues (-noōz/, -nyoōz/; Fr. -ny/). 1. the part of an artless, innocent, unworldly girl or young woman, esp. as represented on the stage. 2. an actress who plays such a part or specializes in playing such parts. Also, in/genuo. [1840-50; e.F. fem of ingénu < L ingenuus native, inborn, etc.; see ingenuous

inege-nu-i-ty (in/je no5/i tē, -ny50/-), n., pl. -ties for 3. 1. the quality of being cleverly inventive or resource-ful; inventiveness: a designer of great ingenuity. 2. cleverness or skillfulness of conception or design: a device of great ingenuity. 3. an ingenious contrivance or device. 4. Obs. ingenuousness. [1500-1600; - L ingenuitàs in nate virtue, etc. (see ingenuous, -irv); current senses by assoc. with ingenious.

in-gen-u-ous (in jen/yoo es), adj. 1. free from reserve, restraint, or dissimulation; candid; sincere. 2. artless; innocent; naive. 3. Obs. honorable or noble. [1590-1600; < L. ingenuus native, free-born, honorable, frank, equiv. to in. In.<sup>2</sup> + gen. (base of gignere; see INGENIOUS) + -uus deverbal adj. suffix; see -ous) —ingen/u-ous-ness, n.
—Syn. 1. frank, straightforward, open. 2. guileless.

age. See ingenious.

in-ger-soll (ing/gər sòl/, -səl/, -səl), n. Robert Green, 1833-99, U.S. lawyer, political leader, and orator.

in-gest (in jest'), v.t. 1. to take, as food, into the body (opposed to egest). 2. Aeron. to draw (foreign matter) (opposed to egest). 2. Aeron to draw (foreign matter) into the inlet of a jet engine, often causing damage to the engine. [610-20; c. Lingestus ptp. of ingerer to throw or pour into. See IN-1 CEST] —In-gest/l-ble, adj. —In-gest/ton, n. —In-gest/tve, adj.

in-ges-ta (in jes/ta), n.pl. substances ingested. [1720-30; < NL, neut. pl. of L ingestus. See ingest]

in-ges-tant (in jes/tent), n. something that is ingested, esp. a substance that may be associated with an allergic reaction. [INGEST + -ANT]

in-gle (ing/gel), n. Chiefly Brit. Dial. 1. a fire burning in a hearth. 2. a fireplace; hearth. [1500-10; < Scot-Gael aingeal fire]

in-gie-nook (ing/gel nook'), n. a corner or nook near a fireplace; chimney corner. [1765-75; INGLE + NOOK] in-gle-side (ing/gol sid/), n. Chiefly Brit. Dial. a fire-side. [1740-50; INGLE + SIDE']

in-gle-wood (ing/ge) wood/), n. a city in SW California, near Los Angeles. 94,245.

ma, near Los Angeies. 94,220.

In-glori-OUS (in glòr'ē sa. -glòr'-), edj. 1. shameful; disgraceful: inglorious retreat. 2. not famous or honored. [1565-75; < L inglorius See IN-<sup>5</sup>. GLORIOUS] —inglorit-ous-ty, edv. —in-glori-ous-tyses, n.
—Syn. 1. dishonorable, ignominious. —Ant. 1. admirable, praiseworthy.

ing-mar (ing/mār), n. a male given name.

in-goal (in/gol/), n. Rugby. the area at either end of the field between the goal line and the dead-ball line. [1896-1900]

In God' We' Trust', 1. a motto appearing on U.S. currency. 2. motto of Florida. [1860-65]

in-go-ing (in-go-ing), adj. going in; entering. [1300–50; ME; see IN-1, GOING]

in-got (ing/got), n. 1. a mass of metal cast in a convenient form for shaping, remelting, or refining.—u.t. 2. to make ingots of; shape into ingots. [1350-1400; ME: like, (something) poured in, equiv. to in- IN-1 + got(e) a stream, OE \*gota, akin to géotan to flow; c. G giessen, Goth giutan, ON gióta to pour]

in'got Vron, an iron of high purity made by a basic open-hearth process. [1875-80]

in-graft (in graft/, -gräft/), v.t. engraft. —in-graft/ment, in/graf-ta/tion, n.

ment, in grain (v. in grain; adj. n. in grain), v.t. 1. to implant or fix deeply and firmly, as in the nature or mind.
—adj. 2. ingrained, firmly fixed. 3. (of fiber or yarn) dyed in a raw state, before being woven or knitted. 4. made of fiber or yarn so dyed: ingrain fabric. 5. (of carpets) made of ingrain yarn and so woven as to show a different pattern on each side; reversible. —n. 6. yarn, wool, etc., dyed before manufacture. 7. an ingrain carpet. Also, engrain (for defs. 1, 2). [1760-70; orig. phrase (dyed) in grain (ie., with kermes)]
—5yn. 1. infuse, inculcate, imbue.

— syn. I. iniuse, incuicate, imoue inigralned (in grand/, adj. 1. firmly fixed; deep-rooted; inveterate: ingrained superstition. 2. wrought into or through the grain or fiber. Also, engrained (1590-1600; INGRAIN + -ED<sup>2</sup>) — im-grained-ly (in grandide, -grand/-), adv. — in-grain/ed-ness, n.

In-gram (ing/grem), n. a male given name.

in-grate, (in'grat), n. 1. an ungrateful person. —adj. 2. Archaic, ungrateful. [1350-1400; ME ingrat < L ingratus ungrateful. See in-1, Gaartsful. —in'grate-iy, adv.

adv.

in-gra-ti-ate (in grā/shē āt/), v.t., -at-ed, -at-ing, to establish (oneself) in the favor or good graces of others, esp. by deliberate effort (usually fol, by with): He ingratiated himself with all the guests. [1615-25; perh.
L in grātiam into favor, after It ingraziare. See IN, GRACE, -AT-1] —In-gra-ti-a-to-ry (in grā/shē a th/ē, -tōr/ē), adj.

in-grat-i-tude (in grat/i tood/, -tyood/), n. the state of being ungrateful; unthankfulness. [1175-1225; ME < ML ingrātitūdō. See IN-², GRATITUDE]

ML ingratitida. See IN-, GAATTUDE;
In-gre-di-ent (in grā-dē ent), n. 1. something that enters as an element into a mixture: Flour, eggs, and sugar are the main ingredients in the cake. 2. a constituent element of anything; component: the ingredients of political success. [1425-75; late ME < L ingredient. (s. of ingredient), pp. of ingredi to go or step into, commence, equiv. to in-in-in-ingredient. going, see GRADIENT]
— Syn. 1. See element. — Ant. whole.

In-gres (an/gr), n. Jean Au-guste Do-mi-nique (zhän ö gyst/ do me nek/), 1780-1867, French painter.

in-gress (in gres), n. 1. the act of going in or entering.

2. the right to enter. 3. a means or place of entering: entryway 4. Astron. immersion (def. 5). [1400-50, late ME < 1. ingressus a going in, commencing, equiv. to ingred., s. of ingred to go or step into, commence (see In.\*, GRADIENT) + -fus suffix of v. action, with -di->ss-] —-in-gres-sion (in gresh'an), n.

In-gress-slee (in gress'iv), adj. 1. of, pertaining to, or involving ingress. 2. Phonet. (of a speech sound) produced with air being taken into the mouth, as some clicks (opposed to egressive). [INGRESS + -IVE] —ingress'sive-ly, adv. —in-gress'sive-ness, n.

In grid (ing'grid), n. a female given name.

In-group (in'groop'), n. 1. a narrow exclusive group; clique. 2. Sociol. a group of people sharing similar interests and attitudes, producing feelings of solidarity, community, and exclusivity. Cf. out-group. Also, in'group'. [1905-10; IN-' + GROUP]

in-grow-ing (in'grō'ing), adj. 1, growing into the flesh: an ingrowing nail. 2. growing within or inward. [1865-70; IN-1 + GROWING]

in-grown (in/gron/), adj. 1. having grown into the flesh: an ingrown toenail. 2. grown within or inward. flesh: an ingrown toenail [1660-70; IN-1 + GROWN]

in-growth (in'groth'), n. 1. growth inward. 2. something formed by growth inward. [1865-70; In-1 + growth]

in-gui-fial (ing/gwe nl), adj. of, pertaining to, or situated in the groin. [1675-85; < L inguinālis of the groin, equiv. to inguin- (s. of inguen) swelling in the groin, groin (c. Gk adén gland; cf. adenoid) +-ālis-aLi

in guinal her nia. Pathol. a common type of hernia in which a loop of the intestine protrudes directly through a weak area of the abdominal wall in the groin

in-gulf (in gulf), v.t. engulf.

In-gulf (in guilf), v.t. engulf.

In-gur-gi-tate (in gur/ji tāt/), v., -tat-ed, -tat-ing,

-v.t. 1. to swallow greedily or in great quantity, as
food. 2. to engulf, swallow up: The floodwaters ingurgitated trees and houses. -v.i. 3. to drink or eat
greedily, guzzle; swill. [1550-70; < L ingurgitātus ptp.
of ingurgitāre to fill, flood, drench with a stream of liquid, equiv. to in- 1n-2 + gurgit- (s. of gurges) whirlpool,
flood + -ātus -ATE¹] —ingur-gi-tat-tion, n.

liogus † -ditte -ditte

necnen. z. the Caucasian language of the Ingush.

Ing-ve-on-lc (ing've on'ik), adj. of or pertaining to Old English, Old Frisian, and Old Saxon, taken collectively. Also, Ing've-on'ic, Ing-we-on-ic, Ing-we-on-ic (ing'we on'ik). (1930-35; after L Inguacoñez (Pliny), Ingacoñez (Tacitus) a Germanic tribal group, taken to mean "adherents of "Ingwaz," prob. a god; cf. OE Ing name of a rune, ON Ing- element in personal names; see-IC]

Concise pronunciation her: act, cape, dare, part; sot, equal; if, ice; ox, over, order, oil, book, book, out; up, tree; child; sing; shoc thin, that; tha sin treasure, s = a as in clone, e as in system, i as in easily, o as in gallop, u as in circus; \*as in fire (fi\*t), hour (ou\*t). I and n can serve as sylbabic consonants, as in cradle (krād'l), and button (out'n). See the full key inside the front cover.